

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of effect of NB-UVB with and without topical Latanoprost solution or placebo in Vitiligo Patients: a triple-blind clinical trial study

Protocol summary

Study aim

To compare the effect of NB-UVB with and without topical Latanoprost solution or placebo in Vitiligo Patients

Design

This is a triple-blind randomized clinical trial, phase II, in which 30 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with Vitiligo who will refer to Sina Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be triple-blinded so that neither patients nor the physician who will examine the patients and data analyzer will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 12 to 70 years Vitiligo lesions with at least one lesions on each side Involving at least 20% of the body surface Exclusion criteria: Malignant skin disease Failure of the previous radiotherapy Pregnancy or breastfeeding Hepatic or renal disease Lupus Erythematosus Photosensitivity

Intervention groups

Intervention group: NB-UVB radiation at a dose of 0.3 J/cm² (wavelength from 311 to 313 nm) for a maximum of 3 minutes three times a week for three consecutive months with a Latanoprost solution 0.005% twice a day for three consecutive months Control group: NB-UVB radiation at a dose of 0.3 J/cm² (wavelength from 311 to 313 nm) for a maximum of 3 minutes three times a week for three consecutive months with a normal saline solution twice a day for three consecutive months

Main outcome variables

Improvement of Vitiligo lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N283**

Registration date: **2019-05-29, 1398/03/08**

Registration timing: **prospective**

Last update: **2019-05-29, 1398/03/08**

Update count: **0**

Registration date

2019-05-29, 1398/03/08

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of NB-UVB with and without topical Latanoprost solution or placebo in Vitiligo Patients: a

triple-blind clinical trial study

Public title

Comparison of effect of NB-UVB with and without topical Latanoprost solution or placebo in Vitiligo Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 12 to 70 years Vitiligo lesions with at least one lesions on each sides Involving at least 20% of the body surface

Exclusion criteria:

Malignant skin disease Failure of previous radiotherapy Pregnancy or breastfeeding Hepatic or renal disease Lupus Erythematosus Photosensitivity

Age

From **12 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the right and left sides of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "right" on one sheet and "left" on another. Then, by referring every patient, one of the sheets will be randomly taken. According to whether the sheet is taken right or left is assigned to the intervention group and the other side to the control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Thus, the trial will be run as triple blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-05-18, 1397/02/28

Ethics committee reference number

IR.UMSHA.REC.1398.165

Health conditions studied

1

Description of health condition studied

Vitiligo

ICD-10 code

L80

ICD-10 code description

Vitiligo

Primary outcomes

1

Description

Improvement of Vitiligo lesions

Timepoint

3 months after the intervention

Method of measurement

With physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: NB-UVB radiation at a dose of 0.3 J/cm² (wavelength from 311 to 313 nm) for a maximum of 3 minutes three times a week for three consecutive months with a Latanoprost solution 0.005% twice a day for three consecutive months

Category

Treatment - Drugs

2

Description

Control group: NB-UVB radiation at a dose of 0.3 J/cm² (wavelength from 311 to 313 nm) for a maximum of 3 minutes three times a week for three consecutive months with a normal saline solution twice a day for three consecutive months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital in Hamadan City

Full name of responsible person

Dr Hanieh Karimi

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

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6517838695

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+98 81 3827 4184

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haniehkari67@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Hanieh Karimi

Position

Resident of Dermatology

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Pedram Alirezaei

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Dermatologist

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available